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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,989

08/29/2006

Walter Christian Babcock

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04/21/2009

CHERNOFF, VILHAUER, MCCLUNG & STENZEL

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EXAMINER

MENON, KRISHNAN S

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

04/21/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,989	<b>Applicant(s)</b> BABCOCK ET AL.	
	<b>Examiner</b> Krishnan S. Menon	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8,9 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8,9 and 11-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/2/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Claims 1,3-5,8,9,11-15 are pending, of which 14 and 15 are withdrawn, as amended 4/2/09

#### ***Claim Rejections - 35 USC § 102/103***

1. Claims 1,3-5, 9, 12, and 13 rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al "A comparative study of artificial membrane permeability assay for high throughput profiling of drug absorption potential", Eur. J. Med. Chem. 37 (2002) 399-407.

This reference teaches a method of evaluating a pharmaceutical composition in a multi-plate well having hydrophilic membranes – see: "2.2. Artificial membrane permeability assay" in page 400. Feed solution is the donor solution; permeate solution is the receiving solution.

The reference uses a hydrophilic PVdF membrane which is commercially available from Millipore, and also teaches about hydrophobic membranes as having slower permeation rate - see paragraph 3.1 on page 401. This PVdF membrane is a hydrophobic membrane made hydrophilic, because PVdF material is hydrophobic. Regarding the permeate solution, the reference does not explicitly state what it is, but it appears to be octanol from the introduction in page 399 and paragraph 2.4 in page 401.

Membrane pore size claimed is in the microporous range – and the Millipore multiwell plate used in the reference is a commercially available microporous membrane plate.

Contact angles recited are inherent in the membrane used in the reference – membrane is hydrophilic – see paragraph 2.2 at page 400. The receptor-side of this membrane is coated with lecithin in dodecane - which makes the receptor (or permeate-side) hydrophobic.

About the distribution or partition coefficients – see the table in the reference.

Aqueous solution is a phosphate buffer. Drug solubility – see the different drugs in the table.

2. Claims 1,3-5,8,9,11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kallury et al (US 7,468,281) and Zhu.

The teachings of Zhu are described above in the rejection paragraph 1.

Kallury teaches sample purification and analysis of drugs etc., (abstract) using multiwell plates with hydrophilized hydrophobic membranes as claimed. Liquid-liquid extraction – see column 3, lines 47-60. Microporous membranes – column 4, lines 55-67. Making the membrane surface hydrophobic or hydrophilic depends on the nature of the analyte - see column 16, lines 21-49. Choice of the solvent or permeate solution would also depend on the drug being extracted, and would be within the skill of one ordinary skill in the art. See liquid-liquid extraction in column 3, lines 47-60 and column 8, line 66 – column 9, line 11.

It would be obvious to combine the teachings of these references to arrive at applicant's invention because such combination would result in no more than predictable results.

### ***Response to Arguments***

Applicant's arguments filed 4/2/09 have been fully considered but they are not persuasive.

Regarding the Zhu reference, since Zhu uses a Millipore PVdF membrane, which is a hydrophobic membrane made hydrophilic, and which what is suggested in applicant's specification, the argument is not persuasive.

Arguments about the Kallury reference appears to be in error – there is no error in the rejection , and Kallury teaches what is discussed in the columns and lines cited in the rejection. Column 5, lines 59-61 and beyond teach a whole lot more details of hydrophobic membranes and how to make them hydrophilic, contrary to what is argued.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1797

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/  
Primary Examiner, Art Unit 1797